

Remarks

The Examiner has requested that Applicant and the Assignee of this application provide certain information that the Examiner has determined to be reasonably necessary to the examination of this Application. The materials identified below are also set forth in an Information Disclosure Statement filed herewith. As noted by the Examiner, the requirements under 37 C.F.R. 1.97 are waived for the documents identified therein. Applicant addresses each of the Examiner's requests in the order in which it was made.

I. Publications Authored or Co-Authored by Applicant

a. Pankaj Prakash, Ph.D., and Bruce Hoff, Ph.D., "Application Note GS10: Microarray Gene Expression Data Mining with Cluster Analysis using GeneSight," BioDiscovery, Inc., 2002, a copy of which is provided.

II. Publications Relied Upon by Applicant

No particular publication was relied upon to developed the Applicant's invention.

III. Publications Relied Upon to Draft Claimed Subject Matter

No particular publication was relied upon to draft the claimed subject matter.

IV. Prior Art Search

A prior art search was conducted by Applicant in preparing a response to the Examiner's request. The following three articles were found.

a. SAS Procedure FASTCLUS, "SAS/STAT 9.1 User's Guide," SAS Institute Inc., 2004, available at http://support.sas.com/documentation/onlinedoc/91pdf/index_913.html#base.

b. Javier Herrero, Alfonso Valencia and Joaquín Dopazo, "A Hierarchical Unsupervised Growing Neural Network for Clustering Gene Expression Patterns," Bioinformatics, vol. 17, no. 2, pp. 126-136, Oxford University Press, 2001, available at <http://bioinformatics.oupjournals.org/cgi/reprint/17/2/126>.

c. Michael B. Eisen, Paul T. Spellman, Patrick O. Brown, and David Botstein, "Cluster Analysis and Display of Genome-wide Expression Patterns," Proc. Natl. Acad.

Sci. USA, vol. 95, pp. 14863–14868, December 1998, available at <http://www.pnas.org/cgi/content/full/95/25/14863>.

The following twenty-two (22) patents were also found as part of the above-referenced search. Of these, USPN 6,453,241 and USPN 6,263,287 relate to analysis and clustering of genomic data. Copies of these patents are provided.

- d. USPN 6,789,069
- e. USPN 6,760,715
- f. USPN 6,714,925
- g. USPN 6,683,455
- h. USPN 6,673,549
- i. USPN 6,632,600
- j. USPN 6,475,736
- k. USPN 6,470,277
- l. USPN 6,462,187
- m. USPN 6,453,241
- n. USPN 6,389,428
- o. USPN 6,341,256
- p. USPN 6,263,287
- q. USPN 6,223,186
- r. USPN 6,222,093
- s. USPN 6,150,179
- t. USPN 6,100,383
- u. USPN 6,040,176
- v. USPN 5,880,268
- w. USPN 5,869,262
- x. USPN 5,811,517
- y. USPN 5,773,218

V. *GeneSight Products and User Manuals*

The following table sets forth the major releases of the GeneSight Products. Of these, GeneSight 3.0 was the first to incorporate Applicant's invention.

Version	Date
GeneSight 1.0	June 30, 1998
GeneSight 2.0	December 14, 2000
GeneSight 3.0	August 31, 2001
GeneSight 4.0	July 31, 2003
GeneSight 4.1.6	September 29, 2004

The following versions of the Users Manual were readily available and are provided in response to this request.

- a. "GeneSight Users Manual," Version 1.3b, BioDiscovery, Inc., 1999.
- b. "GeneSight Users Manual," Version 2.1, BioDiscovery, Inc., 2001.
- c. "GeneSight Users Manual," Draft #1 of Version 3.0, BioDiscovery, Inc., August 31, 2001.
- d. "GeneSight Users Manual," Draft #1 of Version 3.1.3, BioDiscovery, Inc., March 28, 2002. **NOTE:** The date on the face of this Users Manual, "March 28, 2001" is erroneous. The actual date is **March 28, 2002**. This error is supported in part, by the "Copyright Notice" on the second page, which indicates a copyright of 1997-2002 as well as the fact that an earlier version of the product, Version 3.0, wasn't released until August 31, 2001.
- f. "GeneSight Users Manual," Version 3.5, BioDiscovery, Inc., September 3, 2002.
- g. "GeneSight Users Manual," Version 4.0, BioDiscovery, Inc., October 2003.
- h. "GeneSight Users Manual," Version 4.1, BioDiscovery, Inc., 2003.

To the extent that the claimed invention is an "improvement" over the prior art, Applicant submits that the specification as filed provides an adequate explanation of the claimed invention and its "improvements" over the prior art.

Conclusion

Applicant believes that a full and complete response has been made to the Examiner's request to the extent that information complying with the request was reasonably necessary to properly examine or treat the matter or was readily available.

Applicant requests favorable action with regard to the pending claims. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned representative at the number provided.

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Respectfully submitted,


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